New Diagnoses of Connective Tissue, Rheumatoid, and Autoimmune Disease

Pt. ID	Patient Information	Diagnosis	Time to Onset of Diagnosis	Rupture status	Summary	Adverse Events
	Cohort: Augmentation **DOS** **Implant Type:** textured round gel **Placement:** subglandular **MRI Substudy:** YES **MRI Scan Dates:** **Investigator**	Hashimoto's Thyroiditis	17 months (date reported : April 2002)	No rupture	Hashimoto's thyroiditis diagnosed at 2 year visit. Documented with rheumatology consult.	new diagnosis of rheumatic diseas R- unac y low nipple sensit
	Cohort: Augmentation **DOS:** **Implant Type:** smooth round gel **Placement:** subglandular **MRI Substudy:** NO **MRI Scan Dates** **Investigator:**	Rheumatoid arthritis	19 months (date reported. May 2003)	No rupture	At her two year visit, this patient reported multiple symptoms and she was referred to a rheumatologist. Doctor's notes state the patient says she probably had symptoms prior to surgery, although she did not report any at her baseline visit. Reported seronegative rheumatoid arthritis at 2 year visit.	New diagnosis of rheumatic disease 5/2003 Bilateral Baker III capsular contr.
	Cohort: Augmentation **Implant Type:** smooth round gel **Placement:** subpectoral **MRI Substudy:** NO **MRI Scan Dates:** n/a **Investigator:**	Hypothyroidism	32 months (date reported: June 2002)	Not scanned	At the two year visit, this patient reported multiple symptoms and she was referred to a rheumatologist. Rheumatoid arthritis reported at 2 year visit. Arthritis not mentioned in 2-year rheumatology consult. Consult was reviewed by a rheumatology expert who indicated patient had hypothyroidism and as a result has thyroiditis, which is autoimmune in origin.	New diagnosis of rheumatic disea
	Cohort: Revision **DOS** **Implant Type:** textured round gel **Placement:** submuscular **MRI Substudy:** YES **MRI Scan Dates:** **Investigator**	Fibromyalgia	12 months (date reported: 2002)	No rupture	At her two year visit, this patient reported multiple symptoms and she was referred to a rheumatologist who confirmed diagnosis of fibromyalgia	New diagnosis of rheumatic

Pt. ID	Patient Information	Diagnosis	Time to Onset of Diagnosis	Rupture Status	Summary	Adverse Events
	Cohort: Revision **DOS:** **Impla** mooth round gel **Placement:** submuscular **MRI Substudy:** NO **MRI Scan Dates:** n/a **Investigator**	Pyoderma gangrenosum	12 months (date reported: June 2002)	No scan	Pyoderma gangrenosum diagnosed at 1 year. Dermatologist treating her with steroids for pyoderma gangrenosum. A rheumatology expert reviewed the documents and said this patient could have an autoimmune disease, and it is usually associated with IBS or Crohn's disease. To be conservative, it is being reported as a new diagnosis of rheumatic disease.	New diagnosis of rheumatic disease 2/2002 Left breast pain not associated with other complication 8/9/01 Infection 7/30/01
	Cohort: Reconstruction **DOS:** 11/13/01 **Implant Type:** textured round gel **Placement:** submuscular **MRI Substudy:** YES **MRI Scan Dates:** 7/25/02, 8/26/03 **Investigator:** ıle	Fibromyalgia	9 months (date reported: July 2002)	No rupture	At the 1 year visit, patient reported multiple symptoms and was referred to a rheumatologist who confirmed diagnosis of fibromyalgia.	Asymmetry on Right side 1/28/02

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)
		0 0 1			

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**
If YES, complete Adverse Event Report.

RHEUMATIC DISEASE		NO	YES	DATE OF ONSET (if known) month	year
Connective Tissue Disorders:	SLE	☐	☐		
	Sjogren's Syndrome	☐	☐		
	Scleroderma	☐	☐		
	Polymyositis	☐	☐		
	Other Connective Tissue Disorders	☐	☐		
Inflammatory Arthritis:	Rheumatoid Arthritis	☐	☐		
	Crystalline Arthritis	☐	☐		
	Infectious Arthritis	☐	☐		
	Spondyarthropathies	☐	☐		
	Other Inflammatory Arthritis	☐	☐		
Non-Inflammatory Rheumatic Conditions:	Osteoarthritis	☐	☐		
	Fibromyalgia	☐	☐		
	Chronic Fatigue	☐	☐		
	Other Mechanical or Degenerative	☐	☐		
Other, specify: ___		☐	☐		
Other, specify: ___		☐	☐		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who mad

Name: _____

Address _____

_____

Phone _____

MIC III PT> MRT402-014

ARTHRITIS AND COLLAGEN VASCULAR DISEASES

December 10, 2002

[redacted]

[redacted] whom you so kindly referred, was seen for rheumatologic evaluation on December 10, and the following is a summary of my findings and recommendations.

This 33-year-old woman gave a history of having bilateral breast implants in November of 2000. She has done very well with these and is satisfied with the results However, in May of 2002, she developed evidence of Hashimoto's thyroiditis, with an elevated TSH level and an elevated thyroid antibody level as well. On direct questioning, she has no clinical symptoms to suggest other autoimmune diseases except for mild muscle aching which she has had over the last two months.

The additional medical history reveals that she has had elevated lipid values. In February of 1999 she had anterior cruciate ligament repair in the left knee following a ski accident, and in September of 2001 she again had surgery on the left knee for a meniscal tear from a soccer injury.

She is allergic to sulfa.

There is no family history of any significant arthritis.

The physical examination showed a 33-year-old woman with a blood pressure of 110/80, pulse 60, temperature 98. She was five feet, three inches in height and 124 pounds in weight. The general physical examination showed the bilateral breast implants. The musculoskeletal examination showed evidence of prior surgery involving the left knee, but no evidence of synovitis involving any joints of the upper or the lower extremities. She had some tightening of the paracervical and trapezius musculature felt to be related to stress.

Laboratory studies done in Santa Cruz on May 23, 2002 showed an elevated value for thyroid peroxidase and a normal value for thyroglobulin AB. TSH

RE: [redacted]

was also elevated at that time at 54.37. On November 20, 2002, an ANA was 0.3. HIV antibody was negative. A CBC was normal and the sedimentation rate was 12.

Cholesterol levels in May of 2002 showed a total cholesterol of 243, triglycerides 114, HDL cholesterol 55, and LDL cholesterol 165.

No x-rays were taken here.

It is my impression that [redacted] has the following:

1. A history of bilateral breast implants in November of 2000 with good results.

2. History of the development of Hashimoto's thyroiditis in May of 2002, with seemingly adequate control on Synthroid 1 milligram daily.

3. Hyperlipidemia. These studies will need to be repeated once her thyroid is adequately regulated

4. Despite the development of Hashimoto's thyroiditis, I could no find evidence of any other autoimmune disease.

5 History of two surgical procedures on the left knee, including an anterior cruciate ligament repair and a meniscal tear repair.

6. History of sulfa allergy. The patient should therefore not take Celebrex in the future.

In order to assess her status further, I did an immunologic profile and asked her to call me in two weeks so that I can give her those results. Copies of those laboratory studies will be forwarded to your office.

Many thanks for allowing us to share in her care. I did not give her another appointment to return here, but would be happy to see her again any time you may feel it indicated.

Best regards,

P.

sr

[redacted]

cc

[redacted]

901726

[redacted]

MRI BREAST BILATERAL

HISTORY: MENTOR CORE GEL BREAST STUDY

TECHNIQUE: Examination performed on the Siemens 1.5 T Vision unit.

Sagittal and axial T2 weighted sequences were obtained.

FINDINGS: The patient has bilateral breasts implants. The implants are not fully distended and have multiple folds and radial folds. There is no extraluminal fluid or abnormal signal seen. There is no fluid collection or cyst. No other masses or lesions are identified.

The implants are not subpectoral.

IMPRESSION: Bilateral breast implants but no evidence of leakage or rupture.

RADIOLOGIC CONSULTATION

MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	[illegible]	PATIENT NO
	10-009	0 | 0 | 1		[redacted]

MRI EVALUATION

Patient's Date of Birth: [redacted]

MRI Reviewer: _____ _____

Date of MRI Evaluation: 1 \| 1 \| 2004 (month \| day \| year)

Scan Quality (check one):
- 1 ☑ Good
- 2 ☐ Adequate
- 3 ☐ Inadequate

	RIGHT ☐ Not Implanted with Study Device	LEFT ☐ Not Implanted with Study Device
Device Placement:	1 ☐ Submuscular 2 ☒ Subglandular	1 ☐ Submuscular 2 ☒ Subglandular
Implant Type:	1 ☐ Smooth 2 ☒ Siltex	1 ☐ Smooth 2 ☒ Siltex
Implant Evaluation:	1 ☑ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)	1 ☑ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 ☑ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone	1 ☑ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone

Notes: _____

_____

_____ _____

_____ _____ 06 \| 18 \| 2003 (month \| day \| year)

Revi... [illegible]

This study was not designed to detect breast cancer, and so the findings and impressions here should not replace routine screening mammography and clinical examination. Some implant ruptures and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method.

WHITE ORIGINAL MENTOR AFFILIATE YELLOW MENTOR PINK INVESTIGATOR SITE
8/1/00

MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.
	10-009	0 | 0 | 1			[redacted]

MRI EVALUATION

Patient's Date of Birth: [redacted] (month / day / year)

MRI Reviewer: _____

Date of MRI Evaluation: 01 / 11 / 2010 (month / day / year)

Scan Quality (check one):
1. ☐ Good
2. ☒ Adequate
3. ☐ Inadequate

	RIGHT	LEFT
	☐ Not Implanted with Study Device	☐ Not Implanted with Study Device
Device Placement:	1 ☐ Submuscular 2 ☒ Subglandular	1 ☐ Submuscular 2 ☒ Subglandular
[redacted]		
Implant Evaluation:	1 ☒ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)	1 ☒ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture. *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 ☒ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone	1 ☒ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone

Notes: _____

Should double images Seq

Reviewer's Signature _____ 03 / 21 / 2010 (month / day / year)

This study was not designed to detect breast cancer, and so the findings and impressions here should not replace routine screening mammography and clinical examination. Some implant ruptures and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method

WHITE ORIGINAL MENTOR AFFILIATE YELLOW MENTOR PINK INVESTIGATOR SITE
8/7/00

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT			
ATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	SITE NO:	PATIENT NO:	PATIENT INITIALS:

RHEUMATOLOGY SYMPTOMS (Page 1 of 2)

1 ☐ No symptom ... ed to ...

Please check any **current** symptoms which:
1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	☐	☐			☐	☐
Fatigue	☐	☒	11	02	☐	☐
Insomnia	☐	☒	11	02	☐	☐
Weakness	☐	☐			☐	☐
Exhaustion	☐	☐			☐	☐
Joint swelling	☐	☐			☐	☐
Heel pain	☐	☐			☐	☐
Frequent muscle cramps	☐	☐			☐	☐
Numbness of feet	☐	☐			☐	☐
Ringing in ears	☐	☐			☐	☐
Pain/grittiness in eyes	☐	☐			☐	☐
Dryness of eyes, nose	☐	☐			☐	☐
Pain on swallowing or chewing	☐	☐			☐	☐
Neck pain/stiffness	☐	☐			☐	☐
Pain on breathing	☐	☐			☐	☐
Heart murmurs	☐	☐			☐	☐
Loss of appetite	☐	☐			☐	☐
Persistent fever	☐	☐			☐	☐
Night sweats	☐	☐			☐	☐
Generalized aching	☐	☐			☐	☐
Loss of height	☐	☐			☐	☐
Joint pain	☐	☐			☐	☐
Frequent muscle pain	☐	☐			☐	☐

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT

ıTIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS (first middle last)
	10-009	0 0 1		0	

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:
1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	☐	☐			☐	☐
Jaw pain	☐	☐			☐	☐
Open sores	☐	☐			☐	☐
Redness of eyes	☐	☐			☐	☐
Dryness of mouth	☐	☐			☐	☐
Back pain/stiffness	☐	☒	10	02	☐	☐
Severe chest pains	☐	☐			☐	☐
ıronic cough	☐	☐			☐	☐
Difficulty swallowing	☐	☐			☐	☐
Frequent, severe or persistent diarrhea or constipation	☐	☐			☐	☐
Severe rashes	☐	☐			☐	☐
Frequent muscle cramps	☐	☐			☐	☐
Severe dryness of skin	☐	☐			☐	☐
Tender lumps/bumps	☐	☐			☐	☐
Excessive sensitivity to sun	☐	☐			☐	☐
Color changes on hands or feet with cold exposure	☐	☐			☐	☐
Joint pain	☐	☐			☐	☐
Frequent hives	☐	☐			☐	☐
Numbness of hands	☐	☐			☐	☐
Tightness of skin	☐	☐			☐	☐
Jnusual hair loss	☐	☐			☐	☐
Tenderness of scalp	☐	☐			☐	☐
Severe bruising with little or no injury	☐	☐			☐	☐

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
In Patients Who Are Undergoing Primary Breast Augmentation or Primary Breast Reconstruction Revision

DATA CLARIFICATION FORM

PROTOCOL : NR 157681
PATIENT NUMBER : 1
PATIENT INITIALS : [redacted]
DATE SENT : 2/26/2004

STUDY PERIOD	DESCRIPTION	PAGE	RESOLUTION	REF #
2 YEAR VISIT	Severity for NEW DIAGNOSIS OF RHEUMATIC DISEASE has been left blank. Please provide this information.	75	Severity = Moderate Moderate	17648 A 17648A
	Additional Clarification:			

* If a more detailed explanation is needed, please attach

I have reviewed the above and supplied data as indicated. I have retained a copy for the patient's CRF file, and I authorize the CRF to be changed accordingly

INVESTIGATOR'S SIGNATURE : [redacted] DATE : 3-1-04

Above Data Clarification(s) obtained via telephone call to

CRA's SIGNATURE : [redacted] DATE : 3/1/04

Copy w/ corrections

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	2 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO	SITE NO	PATIENT NO	PATIENT INITIALS [first middle last]	
	10-009	0 0 1			[redacted]	☐ No Adverse Events

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
18	☐1 ☒3 ☐2 ☐4	☒0 ☐1 ☐2	☒0 ☐3 ☐1 ☐2	04 / 6/1/2002	☐N/A ☐2 ☐3	☐1 ☐4 ___ days, Date __/__/____ ☒2 Levoxyl / Rheumatology Consult ☐5 ____ ☐3 Procedure Type Code†: ___ Procedure Date: __/__/____	☐1 ☐4 ☒2 ☐3	
	☐1 ☐3 ☐2 ☐4	☐0 ☐1 ☐2	☐0 ☐3 ☐1 ☐2		☐1 ☐2 ☐3	☐1 ☐4 ___ days, Date: __/__/____ ☐2 ____ ☐5 ____ ☐3 Procedure Type Code†: ___ Procedure Date: __/__/____	☐1 ☐4 ☐2 ☐3	

Investigator's Signature _____ month ___ day ___ year ____

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture with Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify Hashimoto's / Thyroiditis
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify _____
29 = Other, specify _____
30 = Other, specify _____

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify _____
92 = Other specify _____

WHITE ORIGINAL MENTOR [illegible]TE YELLOW MENTOR PINK INVESTIGATOR SITE

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	6 MONTH VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	[redacted]	☐ No Adverse Events
	10-009	0 0 1				

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month	day	year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month	day	year
17	☒ 1 ☒ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☒ 0 ☐ 3 ☐ 1 ☐ 2				☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 days, Date __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code†___ Procedure Date: __/__/____	☒ 1 ☐ 4 ~~☐ 2~~ ☐ 3	11	13	2001
	☐ 1 ☐ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 3 ☐ 1 ☐ 2				☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 days, Date __/__/____ ☐ 2 _____ ☐ 5 _____ ☐ 3 Procedure Type Code† ___ Procedure Date: __/__/____	☐ 1 ☐ 4 ☐ 2 ☐ 3			

Investigator's Signature _____ month ____ day ____ year ____

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture with Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast Pain not associated with any other complication
6 = Breast Unacceptably Low Sensitivity
7 = Breast Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Infection
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = [illegible]
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify _____
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify _____
29 = Other, specify _____
30 = Other, specify _____

†SECONDARY PROCEDURE TYPE CODES

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82 = Capsulectomy
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84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify _____
92 = Other, specify _____

MENTOR | Core Gel Breast IDE Clinical Trial | ADVERSE EVENTS | 6 MONTH VISIT

RECEIVED

PATIENT STUDY ID: TRIAL NO. 10-009 | COUNTRY NO 0 0 1 | SITE | PATIENT NO [redacted] | ☐ No Adverse Events

Enter **one** adverse event per line. If the event was experienced at more than one site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure *(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)*** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
19	☒ 1 ☐ 2 ☐ 3 ☐ 4 (5-15-01 case)	☐ 0 ☒ 1 ☐ 2	☒ 0 ☐ 1 ☐ 2 ☐ 3	11 08 00	☒ 1 ☐ 2 ☐ 3	☒ 1 ☐ 2 ☐ 3 Procedure Type Code†:___ ☐ 4 ___ days, Date: __/__/____ ☐ 5 ___ Procedure Date: __/__/____	☐ 1 ☒ 2 ☐ 3 ☐ 4	
	☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2	☐ 0 ☐ 1 ☐ 2 ☐ 3		☐ 1 ☐ 2 ☐ 3	☐ 1 ☐ 2 ☐ 3 Procedure Type Code†:___ ☐ 4 ___ days, Date: __/__/____ ☐ 5 ___ Procedure Date: __/__/____	☐ 1 ☐ 2 ☐ 3 ☐ 4	

Investigator's Signature ___ 05 / 15 / 2001 (month / day / year)

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture **with** Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
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13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
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19 = Nipple—Unacceptably Low Sensitivity
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23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
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29 = Other, specify: ___
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84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: ___
92 = Other, specify ___

New Diagnosis of Connective Tissue Disease Patient Summaries

Study ID
Cohort: Augmentation
DOS: 10/23/01
Implant Type: smooth round gel
Placement: subglandular
MRI Substudy: NO
MRI Scan Dat · 8/29/03
Investigator: (

The patient was enrolled in the Core Gel Study on 10/23/01 in the Augmentation cohort. At the baseline and 1 year visits, no rheumatic symptoms were reported.

At her two year visit, this patient reported the following symptoms: loss of weight without dieting, fatigue, weakness, exhaustion, joint swelling, frequent muscle cramps, pain on swallowing or chewing, loss of appetite, generalized aching, joint pain, frequent muscle pain, jaw pain, back pain/stiffness, frequent diarrhea, frequent muscle cramps and severe bruising with little or no injury. She was referred to a rheumatologist, Dr. Doctor's notes state the patient says she probably had them prior to surgery, although she did not report any at her baseline visit. Seronegative rheumatoid arthritis was reported at the 2 year visit. This diagnosis was made 19 months post surgery.

Dr. Albert notes the following laboratory values:

CPK	62
ESR	5
CMV, IgM, monospot	negative
TSH	normal
WBC	5700 with 68% SEG's, 28% lymphs
Hemoglobin 1	2.6
Platelets	197,000

s consult states that all her studies were negative. The patient was started on MTX 10 mg and Bextra 20 mg.

At the 2 year visit the following symptoms were reported: loss of weight without dieting, fatigue, weakness, exhaustion, joint swelling, frequent muscle cramps, pain on swallowing and chewing, neck pain/stiffness, heart murmurs, loss of appetite, generalized aching, joint pain, frequent muscle pain, numbness of hands, back pain/stiffness, frequent diarrhea, color changes on hands or feet with cold exposure, and severe bruising with little or no injury.

The patient had an MRI scan of the breasts on 8/29/03. No rupture was found.

The patient continues in the Core Gel Study under the care of . She is due for her 3 year follow-up visit in 2004.

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 | C	SITE NO	PATIENT NO	PATIENT INITIALS [redacted]

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE gnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**
If YES, complete Adverse Event Report.

RHEUMATIC DISEASE		NO	YES	DATE OF ONSET (if known) month	year
Connective Tissue Disorders:	SLE	☐	☐		
	Sjogren's Syndrome	☐	☐		
	Scleroderma	☐	☐		
	Polymyositis	☐	☐		
	Other Connective Tissue Disorders	☐	☐		
Inflammatory Arthritis:	Rheumatoid Arthritis	☐	☒	05	2003
	Crystalline Arthritis	☐	☐		
	Infectious Arthritis	☐	☐		
	Spondyarthropathies	☐	☐		
	Other Inflammatory Arthritis	☐	☐		
Non-Inflammatory Rheumatic Conditions:	Osteoarthritis	☐	☐		
	Fibromyalgia	☐	☐		
	Chronic Fatigue	☐	☐		
	Other Mechanical or Degenerative	☐	☐		
Other, specify: _____		☐	☐		
Other, specify: _____		☐	☐		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	2 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.	SITE NO.	PATIENT NO.	PATIENT INITIALS	☐ No Adverse Events
	10-009	0 0 1			[redacted]	

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month	day	year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this event)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month	day	year
18	☐1 ☒3 ☐4 ☐2	☒0 ☐1 ☐2	☒0 ☐3 ☐1 ☐2	5	UNK	2003	☐1 ☐2 ☒3	☐1 ☐2 ☐3 Procedure Type Code†: ☐4 ___ days, Date: __/__/__ ☒5 Rheumatoid Workup Procedure Date: __/__/__	☐1 ☐4 ☒2 ☐3			
	☐1 ☐3 ☐2 ☐4	☐0 ☐1 ☐2	☐0 ☐3 ☐1 ☐2				☐1 ☐2 ☐3	☐1 ☐2 ☐3 Procedure Type Code†: ☐4 ___ days, Date: __/__/__ ☐5 ___ Procedure Date: __/__/__	☐1 ☐4 ☐2 ☐3			

Investigator's Signature: [signature] 09 / 25 / 2003 (month / day / year)

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

*ADVERSE EVENT CODES

1 = Asymmetry
2 = Baker II Capsular Contracture with Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify: Seronegative Rheumatoid Arthritis
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify: ___
29 = Other, specify: ___
30 = Other, specify: ___

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: ___
92 = Other, specify: ___

WHITE ORIGINAL: MENTOR AFFILIATE 8/15/00 YELLOW: MENTOR PINK: INVESTIGATOR SITE

07-10-2003

[redacted]

O/V Follow up

HISTORY: [redacted] is seen with her husband to review her test results. All of her studies were negative. She found that increasing the Bextra helped her morning with the stiffness, but she still is experiencing profound fatigue by the afternoon. She asked me if her silicone gel implants could be the cause of her joint symptoms. She says that to her knowledge they have not leaked, but she has not had any regular imaging study. She did have hardening problems after they were put in 2 years ago.

PHYSICAL EXAM: [redacted] is moving stiffly.
EXTREMITIES: Shoulders show slightly stiff range of motion. Elbows are clear. Wrists and MCP's and PIP's all have trace to 1+ synovitis with a slight reddish purple hue and swelling and tenderness. Knees have the same findings and MTP's.

ASSESSMENT:

1. Seronegative rheumatoid arthritis and I explained to them that this can evolve over time and clarify itself as to the diagnosis such as psoriatic arthritis or other, but that we need to begin treatment. She's going to take MTX 10 mg PO Q week and Bextra 20 mg PO BID. She is warned of potential side effects and toxicity and understands not to drink alcohol. She can not get pregnant.
2. Silicone gel implants – we're going to consult with Dr. Hollingsworth as to what is the best imaging study for her to have and what is recommended now for follow up of silicone gel implants. I explained to her the population based study which did not show a connection between the implants and autoimmune disease, but on an individual bases, I am not sure. Certainly it would not be good if she had leakage and free silicone in her body.

PT had MRI scan negative

06-30-2003

[redacted]

HISTORY: Mrs. [redacted] is a 32 year old Caucasian female who sees [redacted] primary care who is a personal friend and who's husband asked me to evaluate her regarding her symptoms. It seems that 1 month ago, she began experiencing extreme fatigue and muscle soreness and cramping. She s [redacted] ho did blood work and then she went to Hawaii with her husband on a trip and while there began having s [redacted] stiffness in her hands and feet. She stopped taking Zelnorm and though that her calves stopped cramping. When she returned home, she saw Dr. Nagode's PA who gave her a Depo-Medrol shot and Celebrex and 24 hours later she felt a little bit better, but at 48 hours, she started having swelling in her MCP's. By then, she was also having pain and stiffness in her ankles and elbows and intermittently in her shoulders and hips and knees. She has not had any rash throughout this and denies tick exposure, children having recent immunizations, although 1 child did have strep throat 2 to 3 weeks before [redacted] became ill. She has occasional post-nasal drip and sinus pressure for years. She feels her chronic TMJ symptoms are getting worse. She's been constipated all of her life, but has had 1 episode of diarrhea that lasted 10 days in the last few months when they were moving to a new house. There was no blood or mucus in it. On June 10th, her CMP was normal including a CPK of 62. Her ESR was normal at 5. CMV, IgM and monospot negative, TSH normal. White blood cell count 5700 with 68% SEG's, 28% lymphs, hemoglobin 12.6, platelets 197,000. She's always had very cold hands and feet and typically has to wear sock in bed at night. She's not noticed color change in her hands when they are cold, but does have symptoms going in cold stores and during the winter time. She has had 1 miscarriage, but no thrombosis and no biologic false positive VDRL. The rest of her rheumatologic review of systems is negative.

PAST MEDICAL HISTORY: IBS, hiatal hernia.

CURRENT MEDICATIONS: Prevacid 30 mg PO QD, Bextra 20 mg PO QD, Yasmin 28 PO QD, Prenatal vitamin QD, vitamin E 3 QD, vitamin C QD, calcium and Viactiv QD.

ALLERGIES: *None known.*

PAST SURGICAL HISTORY: Tonsillectomy. TAH, breast augmentation.

FAMILY HISTORY: Father has a hiatal hernia. Mother has osteoarthritis and thyroid disease. Grandmother and aunt have breast cancer and a great maternal aunt has rheumatoid arthritis. She's 1/8th Cherokee.

REVIEW OF SYSTEMS: See intake form.

PHYSICAL EXAM: Mrs. Poteet appears her stated age in no acute distress today, but moves stiffly. Weight 134, B/P 112/80.
HEENT: No scalp rash or alopecia. Pupils round & reactive to light. Extra ocular movements are intact. Oral pharynx is clear with a good saliva pool.
NECK: Good range of motion. No abnormal lymphadenopathy, thyromegaly or JVD.
CHEST: Clear throughout.
CARDIOVASCULAR: Regular rate & rhythm without murmur, gallop or rub.
ABDOMEN: Soft, non-tender. No hepatosplenomegaly. Normal active bowel sounds x 4.
EXTREMITIES: Shoulders are stiff with range of motion in all directions. Elbows are clear. Right wrist with trace synovitis. Left wrist is stiff. MCP's stiff, but no swelling, warmth or erythema. PIP's show trace swelling and she only had 75% closure in her PIP's. She has some periungual erythema. She has obvious Raynaud's that is triphasic involving her hands diffusely bilaterally as well as her feet. There are no digital ulcers and there's no clear sclerodactyly at this time, just borderline skin changes distally that are rather subtle and questionable. Hips are clear. Knees show right patellofemoral click and slight medial instability. Ankles are clear. Toes diffusely tender.
SKIN: No rash.
BACK: Normal without scoliosis or SI joint tenderness.

ASSESSMENT:

1. History of joint pain and stiffness that can last hours acute onset that's fairly symmetrical involving large and small joints, but certainly should be screened for rheumatoid arthritis, other autoimmune disease such as lupus or

scleroderma. We'll do a rheumatoid factor, anti-CCP, ANA, anti-SSA, SSB, SM, RNP anti-cardiolipin since she had a miscarriage, CRP and she needs a hepatitis C IgG screen due to other information she shared with me. I have advised her in the interim to increase her Bextra to 20 mg PO BID and I will see her in 1 week to review these test results.

9-JUL-2003 12:15 Page 1

ice, call

Site #: 0100131990 Report: 1/1 Distribute to:

PATIENT: [redacted] ACCOUNT:
CLIENT PATIENT ID: REF DR:
REQ NUMBER: 76689981-18
ID OR ROOM [redacted]
PAGE DOB/AGE: [redacted] 32 YEARS
1 SEX: U HRS:
DATE/TIME COLL: Jul 01 2003 12:30 PM
DATE RECEIVED: Jul 02 2003 03:00 AM
DATE REPORTED: Jul 09 2003
DATE RE-SENT: Jul 09 2003
REPORT STATUS: FINAL REPORT

RESULT NAME	IN RANGE	OUT OF RANGE	REFERENCE	UNITS
Gender not specified, reference ranges default to male where applicable.				
BLOOD CHEMISTRY				
NO HEMOLYSIS DETECTED				
NO LIPEMIA DETECTED				
NO ICTERUS DETECTED				
C-REACTIVE PROTEIN (hs-CRP)		0.86	<= 5.00	MG/L
CVD RISK ASSESSMENT:				
Avg. hs-CRP (mg/L)	Relative Risk			
< 1.00	Low			
1.00 - 3.00	Average			
> 3.00	High			
** THE FOLLOWING COMMENT APPLIES ONLY TO hs-CRP RESULTS THAT ARE BEING USED FOR CVD ASSESSMENT **				
MEASUREMENT OF MARKERS SHOULD BE DONE TWICE (AVERAGING RESULTS), OPTIMALLY TWO WEEKS APART, FASTING OR NONFASTING IN METABOLICALLY STABLE PATIENTS. IF hs-CRP LEVEL IS > 5.00 mg/L, TEST SHOULD BE REPEATED AND PATIENT EXAMINED FOR SOURCES OF INFECTION OR INFLAMMATION. (Circulation 2003;107(3):488-511)				
HEPATITIS TEST				
HEPATITIS C Ab	NEGATIVE		NEGATIVE	
SJOGREN'S SYNDROME ANTIBODIES				
ANTI-SS-A		0.2	<= 2.0	U/ML
ANTI-SS-B		0.3	<= 2.0	U/ML
INTERPRETATION:				
NEGATIVE:	<= 2.0 U/ML			
POSITIVE:	> 2.0 U/ML			
Anti-dsDNA		0		IU/ML
	NEGATIVE		< 30	IU/ML
	BORDERLINE		30 - 50	IU/ML
	POSITIVE		50 - 300	IU/ML
	STRONG POSITIVE		> 300	IU/ML
ENA ANTIBODIES				

- REPORT CONTINUED ON NEXT PAGE -

M9

1/1

PATIENT: [redacted]
CLIENT PATIENT ID: [redacted]
REQ NUMBER: 76851134-16
ID OR ROOM NO: UNKNOWN
PAGE DOB/AGE: [redacted] 32 YEARS
1 SEX: F FASTING: NO HRS:
DATE/TIME COLL: Aug 18 2003 10:15 AM
DATE RECEIVED: Aug 18 2003 04:04 AM
DATE REPORTED: Aug 19 2003
DATE RE-SENT: Aug 19 2003
REPORT STATUS: FINAL REPORT

••• AN ADDITIONAL FAX COPY OF THIS REPORT WAS SENT TO: [redacted] •••
PATIENT PHONE NUMBER:

RESULT NAME	IN RANGE	OUT OF RANGE	REFERENCE	UNITS
BLOOD CHEMISTRY				
NO HEMOLYSIS DETECTED				
NO LIPEMIA DETECTED				
NO ICTERUS DETECTED				
TOTAL BILIRUBIN	0.6		0.2 - 1.3	MG/DL
DIRECT BILIRUBIN	0.1		0.0 - 0.2	MG/DL
AST (SGOT)	11		< 45	U/L
ALT (SGPT)	13		< 45	U/L
ALKALINE PHOSPHATASE	43		40 - 125	U/L
TOTAL PROTEIN	6.8		6.3 - 7.8	G/DL
ALBUMIN	4.5		3.7 - 5.2	G/DL
HEMATOLOGY				
HGB		10.7	12.0 - 16.0	G/DL
HCT		32.2	36.0 - 48.0	%
RBC		3.50	4.20 - 5.40	MILLION/MCL
MCV	91		82 - 102	FL
MCH	30.3		26.0 - 35.0	PG
MCHC	33.2		30.0 - 37.0	G/DL
RDW	14.4		11.5 - 14.5	%
WBC	5.8		4.0 - 11.0	K/MCL
NEUTROPHILS		40	42 - 77	%
LYMPHOCYTES		50	16 - 43	%
MONOCYTES	7		4 - 12	%
EOSINOPHILS	2		0 - 8	%
BASOPHILS	2		0 - 3	%
PLATELET COUNT	181		130 - 400	K/MCL

END OF REPORT FOR POTEET, [redacted]

ble for
appt

5001

ite #: 0100131890 Report: 1/1 Distribute to: .

PATIENT: [redacted]
CLIENT PATIENT ID: 7
REQ NUMBER: 76890881-16
ID OR RO[redacted]
AGE DOB/AGE: [redacted] 2 YEARS
2 SEX: U HRS:
DATE/TIME COLL: Jul 01 2003 12:30 PM
DATE RECEIVED: Jul 02 2003 03.00 AM
DATE REPORTED: Jul 08 2003
DATE RE-SENT: Jul 09 2003
REPORT STATUS: FINAL REPORT

:ESULT NAME	IN RANGE	OUT OF RANGE	REFERENCE	UNITS
ANTI-Sm	<0.1		<= 4.0	U/ML
ANTI-Sm/RNP	0.1		<= 2.5	U/ML
iNA SCREEN	NEGATIVE		NEGATIVE	
MMUNOLOGY				
ANTI-STREPTOLYSIN O	82		0 - 200	IU/ML
RHEUMATOID FACTOR	<10		< 14	IU/ML

AT:
C

800-338-3718
:H.

:ardiolipin Antibody Panel

rdiolipin Antibody Panel

ardiolipin IgA Antibody	<14		<14 APL U/mL
eference range	APL Units/mL		
Negative	<14		
Low Positive	14-18		
Medium Positive	20-80		
High Positive	>80		
:ardiolipin IgG Antibody	<12		<12 GPL U/mL
Reference range	GPL Units/mL		
Negative	<12		
Low Positive	12-18		
Medium Positive	20-80		
High Positive	>80		

The 1999 International Consensus Statement states that one criterion for the serological diagnosis of Definite Antiphospholipid Syndrome is the presence of cardiolipin antibody (ACA) IgG and/or IgM in the blood that are in the medium or high positive ranges on 2 or more occasions, at least 5 weeks apart. Population studies indicate that approximately 8.5% of the normal population are positive for ACA IgG whereas approximately 10.6% of normal pregnancies are positive. Caution should therefore be exercised in interpreting the relevance of low levels of cardiolipin antibodies.

Cardiolipin IgM Antibody	<11		<11 MPL U/mL
Reference range	MPL Units/mL		

- REPORT CONTINUED ON NEXT PAGE -

PATIENT: [redacted] ACCOUNT: T807
CLIENT PA[redacted]
REQ NUMBER: 76009901-16
IO OR ROOM NO: UNKNOWN
AGE DOB/AGE: [redacted]/32 YEARS
3 SEX: U FASTING: NO HRS:
DATE/TIME COLL: Jul 01 2003 12.30 PM
DATE RECEIVED: Jul 02 2003 03:00 AM
DATE REPORTED: Jul 09 2003
DATE RE-SENT: Jul 09 2003
REPORT STATUS: FINAL REPORT

RESULT NAME	IN RANGE	OUT OF RANGE	REFERENCE	UNITS
Negative	<11			
Low Positive	11-19			
Medium Positive	20-80			
High Positive	>80			

The 1989 International Consensus Statement states that one criterion for the serological diagnosis of Definite Antiphospholipid Syndrome is the presence of cardiolipin antibody (ACA) IgG and/or IgM in the blood that are in the medium or high positive ranges on 2 or more occasions, at least 6 weeks apart. Population studies indicate that approximately 8.4% of the normal population are positive for ACA IgM whereas approximately 17% of normal pregnancies are positive. Caution should, therefore be exercised in interpreting the relevance of low levels of cardiolipin antibodies.

Smooth Muscle Ab Titer

Smooth Muscle Ab Titer	1:20		<1:20

CYCLIC CITRULLINATED PEPTIDE(CCP)IGG AB
CYCLIC CITRULLINATED PEPTIDE (CCP) IGG AB, ELISA

CCP IGG	5	UNITS

REFERENCE RANGE: < 20 Units

INTERPRETIVE CRITERIA:

< 20 Units	Antibody Not Detected
> or = 20 Units	Antibody Detected

This assay measures IgG antibodies recognizing a circular peptide containing citrulline, the deimidated form of arginine. CCP antibodies, like rheumatoid factor (RF), are found in approximately 70% of patients with rheumatoid arthritis (RA). However, the specificity of CCP antibodies (>95%) is markedly higher than that of RF (85-90%). CCP antibodies may be detected in the early stages of disease, before RF is detectable. RA patients with CCP antibodies tend to develop more severe disease compared to patients without CCP antibodies. It was recently shown that antikeratin antibodies and antifillagrin antibodies actually recognize citrulline, and are thus identical to CCP antibodies.

This assay was performed using a kit labeled "For Investigational Use Only" by

- REPORT CONTINUED ON NEXT PAGE -

405-038

[redacted]

REPORT STATUS Final

ORDERING PHYSICIAN
M

DOB: [redacted] Age: 32
GENDER: F

SPECIMEN INFORMATION
SPECIMEN: XO3932259C
REQUISITION: 0000633
LAB REF NO:

ID: 47281

CLIENT INFORMATION
00003543

COLLECTED: 06/10/2003 17:00
RECEIVED: 06/10/2003 20:45
REPORTED: 06/16/2003 05:54

Test Name	In Range	Out of Range	Reference Range	Lab
COMPREHENSIVE METABOLIC PANEL				XO
GLUCOSE	89		65-109 MG/DL	
		FASTING REFERENCE INTERVAL		
UREA NITROGEN (BUN)	13		7-25 MG/DL	
CREATININE	0.8		0.5-1.2 MG/DL	
BUN/CREATININE RATIO	16		6-25 (CALC)	
SODIUM	142		135-146 MMOL/L	
POTASSIUM	4.5		3.5-5.3 MMOL/L	
CHLORIDE	106		98-110 MMOL/L	
CARBON DIOXIDE	[redacted]		[redacted]	
CALCIUM	9.7		8.6-10.4 MG/DL	
PROTEIN, TOTAL	7.3		6.1-8.3 G/DL	
ALBUMIN	4.4		3.6-5.1 G/DL	
GLOBULIN	2.9		1.9-4.2 G/DL (CALC)	
ALBUMIN/GLOBULIN RATIO	1.5		0.8-2.0 (CALC)	
BILIRUBIN, TOTAL	0.5		0.2-1.2 MG/DL	
ALKALINE PHOSPHATASE	62		20-125 U/L	
AST	13		2-35 U/L	
ALT	9		2-60 U/L	
CREATINE KINASE, TOTAL	62		0-165 U/L	XO
SED RATE BY MODIFIED WESTERGREN				XO
SED RATE BY MODIFIED WESTERGREN	5		< OR = 20 MM/HR	
	ESR SPECIMENS ARE STABLE FOR 4-6 HOURS AT ROOM TEMPERATURE (12 HOURS IF REFRIGERATED). ESR RESULTS TREND LOWER WITH INCREASED SPECIMEN AGE. CONSIDER USE OF C-REACTIVE PROTEIN TO ASSESS ACUTE PHASE RESPONSES.			
CBC (INCLUDES DIFF/PLT)				XO
WHITE BLOOD CELL COUNT	5.7		3.8-10.8 THOUS/MCL	
RED BLOOD CELL COUNT	4.03		3.80-5.10 MILL/MCL	
HEMOGLOBIN	12.6		11.7-15.5 G/DL	
HEMATOCRIT	36.5		35.0-45.0 %	
MCV	90.6		80.0-100.0 FL	
MCH	31.2		27.0-33.0 PG	
MCHC	34.5		32.0-36.0 G/DL	
RDW	13.6		11.0-15.0 %	

[redacted] XO3932259C

Page 1 - Continued on Pag[redacted]

TJT

405-038

PATIENT INFORMATION [redacted]

REPORT STATUS Final

DOB: [redacted] Age: 32
GENDER: F

REPORTED: 06/16/2003 05:54

Test Name	In Range	Out of Range	Reference Range	Lab
CBC (INCLUDES DIFF/PLT) (Continued)				
PLATELET COUNT	197		140-400 THOUS/MCL	
ABSOLUTE NEUTROPHILS	3882		1500-7800 CELLS/MCL	
ABSOLUTE LYMPHOCYTES	1619		850-3900 CELLS/MCL	
[redacted]				
ABSOLUTE EOSINOPHILS	40		15-500 CELLS/MCL	
ABSOLUTE BASOPHILS	11		0-200 CELLS/MCL	
NEUTROPHILS	65.1		%	
LYMPHOCYTES	28.4		%	
MONOCYTES	2.4		%	
EOSINOPHILS	0.7		%	
BASOPHILS	0.4		%	
CMV IGM ANTIBODY				XO
CYTOMEGALOVIRUS IGM AB BY EIA	NEGATIVE			
	NEGATIVE - NO CMV IGM AB DETECTED EQUIVOCAL - SUGGEST RETEST IN 2-3 WEEKS, IF SUSPECT ACUTE CMV INFECTION. POSITIVE - CMV IGM AB DETECTED.			
	RESULTS FROM ANY ONE IGM ASSAY SHOULD NOT BE USED AS A SOLE DETERMINATE OF A CURRENT OR RECENT INFECTION. BECAUSE IGM TESTS CAN YIELD FALSE POSITIVE RESULTS AND LOW LEVELS OF IGM ANTIBODY MAY PERSIST FOR MORE THAN 12 MONTHS POST INFECTION, RELIANCE ON A SINGLE TEST RESULT COULD BE MISLEADING. IF AN ACUTE INFECTION IS SUSPECTED, CONSIDER OBTAINING A NEW SPECIMEN AND SUBMIT FOR BOTH IGG AND IGM TESTING IN TWO OR MORE WEEKS. LIMITATIONS OF PROCEDURE: 1. POSITIVE TEST RESULTS MAY NOT BE VALID IN PERSONS WHO HAVE RECEIVED BLOOD TRANSFUSIONS OR OTHER BLOOD PRODUCTS WITHIN THE PAST SEVERAL MONTHS. 2. IGM RESPONSES CAN VARY FROM PATIENT TO PATIENT. A NEGATIVE RESULT IN THE CMV IGM ASSAY DOES NOT PRECLUDE THE POSSIBILITY OF A RECENT PRIMARY CMV INFECTION.			
TSH	1.36		MIU/L	XO
			> 20 YEARS 0.40-5.50	
			FOR PREGNANT PATIENTS: FIRST TRIMESTER 0.30-4.50 SECOND TRIMESTER 0.50-4.60 THIRD TRIMESTER 0.80-5.20	
HETEROPHILE, MONO SCREEN	NEGATIVE		NEGATIVE	XO

[redacted]

Page 1 - Continued on Page

[redacted]

REPORT STATUS: Final

DOB: [redacted] Age: 32
GENDER: F

REPORTED: 06/16/2003 08:54

Test Name	Lab
TEST AUTHORIZATION	XC
TEST NAME: WORD	
TEST CODE:	
CLIENT CONTACT:	

THE LABORATORY TESTING ON THIS PATIENT WAS VERBALLY REQUESTED OR CONFIRMED BY THE ORDERING PHYSICIAN OR HIS OR HER AUTHORIZED REPRESENTATIVE AFTER CONTACT WITH AN EMPLOYEE OF QUEST DIAGNOSTICS. FEDERAL REGULATIONS REQUIRE THAT WE MAINTAIN ON FILE WRITTEN AUTHORIZATION FOR ALL LABORATORY TESTING. ACCORDINGLY WE ARE ASKING THAT THE ORDERING PHYSICIAN OR HIS OR HER AUTHORIZED REPRESENTATIVE SIGN A COPY OF THIS REPORT AND PROMPTLY RETURN IT TO THE CLIENT SERVICE REPRESENTATIVE.

SIGNATURE: _____

PERFORMING LABORATORY INFORMATION:

XC QUEST DIAGNOSTICS OF OKLAHOMA 10441 COMMERCE PARKWAY OKLAHOMA CITY OK 73131 LABORATORY DIRECTOR: [redacted], MD

[redacted]

Page 1 End of Report

P.4/4

JUL-

MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.	PATIENT NO.	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO
	10-009	0 0 1		[redacted]	

MRI EVALUATION

Patient's Date of Birth: [redacted]

MRI Reviewer: _____

Date of MRI Evaluation: 08 (month) 29 (day) 2003 (year)

Scan Quality (check one):
- 1 ☑ Good
- 2 ☐ Adequate
- 3 ☐ Inadequate

	RIGHT ☐ Not Implanted with Study Device	LEFT ☐ Not Implanted with Study Device
Device Placement:	1 ☐ Submuscular 2 ☐ Subglandular	1 ☐ Submuscular 2 ☐ Subglandular
Implant Type:	1 ☐ Smooth 2 ☐ Siltex	1 ☐ Smooth 2 ☐ Siltex
Implant Evaluation:	1 ☑ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)	1 ☑ No Evidence of Rupture 2 ☐ Indeterminate Evidence of Rupture 3 ☐ Rupture: *Check one Type:* 1 ☐ Intracapsular 2 ☐ Extracapsular *Check one Condition:* 1 ☐ Uncollapsed 2 ☐ Partially Collapsed 3 ☐ Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 ☑ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone	1 ☑ No Evidence of Extracapsular Silicone 2 ☐ Indeterminate for Extracapsular Silicone 3 ☐ Definite Extracapsular Silicone

Notes: MRI. for Cause

Reviewer's Signature

10 (month) 06 (day) 2003 (year)

This study was not designed to detect breast cancer, and so the findings and impressions here should not replace routine screening mammography and clinical examination. Some implant ruptures and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method.

8/15/00

Name: [redacted]
Phys: [redacted]
Dob: [redacted] Age: [redacted] Sex: F
Acct: [redacted]
Exam Date: 08/2[redacted]/2003 Status: REG REF
Radiology No.: [redacted]
Pat[redacted]

EXAMS: 001189539 MRI BREAST BILAT WITHOUT CONTR
Clinical Data: [redacted] CORE STUDY

MRI BREAST BILATERAL WITHOUT CONTRAST FOR THE MENTOR STUDY - 08/29/03

MRI SEQUENCES:
Axial T2 and fat-suppressed T2 as well as sagittal T2 with water-suppressed pulsing sequences were performed of both breasts using a Siemens 1.5 Tesla magnet and a bilateral breast coil.

RIGHT BREAST: There is a subglandular silicone implant in place. Some prominent folds are demonstrated; however, there is no definite MRI evidence to suggest either intra- or extracapsular rupture of the implant. The breast parenchyma is dense.

LEFT BREAST: On the left there is a silicone implant in place with some prominent folds. There is no definite evidence of intra- or extracapsular rupture of the implant.

Report was stat faxed to [redacted]
1340 hours.

** REPORT SIGNATURE ON FILE 09/05/2003 **
Reported By:
Signed By:

Cc:

Dictated Date/Time: 09/04/2003 (1326)
Transcribed Date/Time: 09/04/2003 (1341)
Transcriptionist: MER TCT
Printed Date/Time: 09/05/2003 (1101)

Plastic, Laser &
Where top training and beautiful results meet

November 20, 2003

Attn: Carolyn Offutt
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA. 93111

Dear Carolyn,

[redacted] was seen in our office on September 3, 2003 for follow-up two-year Core Gel Study. On examination she was found to have Baker II contractures bilaterally, with good contour and symmetry. On completion of her questionnaire, she does note multiple symptoms of arthritis. She has had a rheumatology work-up by [redacted] I have a copy of these findings in her chart and can make them available to you if needed. Basically, the findings were within normal [redacted] has diagnosed this as Seronegative rheumatoid arthritis. I sent her for an MRI which was also normal.

[redacted] initial consult did not disclose any arthritic type symptoms, and this is confirmed by the initial questionnaires. At her two-year follow-up she does state that she probable had these symptoms prior to surgery. We proceeded with surgery based on her denial of any arthritic conditions.

If you should have any questions regarding this matter please feel free to contact my office.

Sincerely,

5009

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT			
PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO 0 0 1	SITE NO	PT NO	PATIENT INITIALS [redacted]

RHEUMATOLOGY SYMPTOMS (Page 1 of 2)

☐ No symptoms; patient not referred to rheumatologist

Please check any **current** symptoms which:
1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	☐	☑	5	2003	☐	☑
Fatigue	☐	☑	5	2003	☐	☑
Insomnia	☐	☐			☐	☐
Weakness	☐	☑	5	2003	☐	☑
Exhaustion	☐	☑	5	2003	☐	☑
Joint swelling	☐	☑	5	2003	☐	☑
Heel pain	☐	☐			☐	☐
Frequent muscle cramps	☐	☑	5	2003	☐	☑
Numbness of feet	☐	☐			☐	☐
Ringing in ears	☐	☐			☐	☐
Pain/grittiness in eyes	☐	☐			☐	☐
Dryness of eyes, nose	☐	☐			☐	☐
Pain on swallowing or chewing	☐	☑	5	2003	☐	☑
Neck pain/stiffness	☐	☑	5	2003	☐	☑
Pain on breathing	☐	☐			☐	☐
Heart murmurs	☐	☐			☐	☐
Loss of appetite	☐	☑	5	2003	☐	☑
Persistent fever	☐	☐			☐	☐
Night sweats	☐	☐			☐	☐
Generalized aching	☐	☑	5	2003	☐	☑
Loss of height	☐	☐			☐	☐
Joint pain	☐	☑	5	2003	☐	☑
Frequent muscle pain	☐	☑	5	2003	☐	☑

MENTOR	Core Gel Breast IDE Clinical Trial	2 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	PATIENT INITIALS
	10-009	0 0 1	[redacted]

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:
1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	☐	☐			☐	☐
Jaw pain	☐	☑	5	2003	☐	☑
Open sores	☐	☐			☐	☐
Redness of eyes	☐	☐			☐	☐
Dryness of mouth	☐	☐			☐	☐
Back pain/stiffness	☐	☑	5	2003	☐	☑
Severe chest pains	☐	☐			☐	☐
Chronic cough	☐	☐			☐	☐
Difficulty swallowing	☐	☐			☐	☐
Frequent, severe or persistent diarrhea or constipation	☐	☑	5	2003	☐	☑
Severe rashes	☐	☐			☐	☐
Frequent muscle cramps	☐	☑	5	2003	☐	☑
Severe dryness of skin	☐	☐			☐	☐
Tender lumps/bumps	☐	☐			☐	☐
Excessive sensitivity to sun	☐	☐			☐	☐
Color changes on hands or feet with cold exposure	☐	☐			☐	☐
Joint pain	☐	☑	5	2003	☐	☑
Frequent hives	☐	☐			☐	☐
Numbness of hands	☐	☐			☐	☐
Tightness of skin	☐	☐			☐	☐
Unusual hair loss	☐	☐			☐	☐
Tenderness of scalp	☐	☐			☐	☐
Severe bruising with little or no injury	☐	☑	[illegible]	2003	☐	☑

MENTOR	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS	1 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO.	SITE NO	PATIENT NO.	☐ No Adverse Events
	10-009	0 0 1		[redacted]	

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = **Secondary Procedure** ***(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)**** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day yr
3	☐ 1 ☒ 3 ☐ 2 ☐ 4	☐ 0 ☒ 1 ☐ 2	☒ 0 ☐ 3 ☐ 1 ☐ 2	7 unk 2002	☒ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 days, Date: __/__/__ ☒ 2 Accolate ☒ 5 Ultrasound ☐ 3 Procedure Type Code†:___ Procedure Date: __/__/__	☐ 1 ☐ 4 ☒ 2 ☐ 3	
3	☐ 1 ☒ 3 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☒ 2	☒ 0 ☐ 3 ☐ 1 ☐ 2	7 unk 2002	☒ 1 ☐ 2 ☐ 3	☐ 1 ☐ 4 days, Date: __/__/__ ☒ 2 Accolate ☒ 5 Ultrasound ☐ 3 Procedure Type Code†:___ Procedure Date: __/__/__	☐ 1 ☐ 4 ☒ 2 ☐ 3	

Investigator's Signature — 11 (month) 06 (day) 2002 (year)

Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.

***ADVERSE EVENT CODES**

1 = Asymmetry
2 = Baker II Capsular Contracture **with** Surgical Intervention
3 = Baker III Capsular Contracture
4 = Baker IV Capsular Contracture
5 = Breast pain not associated with any other complication
6 = Breast—Unacceptably Low Sensitivity
7 = Breast—Unacceptably High Sensitivity
8 = Calcification
9 = Delayed Wound Healing
10 = Extrusion
11 = Granuloma
12 = Hematoma
13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify: _____
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify: _____
29 = Other, specify: _____
30 = Other, specify: _____

†SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explantation with Replacement**
84 = Explantation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: _____
92 = Other, specify: _____

MENTOR | Core Gel Breast IDE Clinical Trial | ADVERSE EVENTS | 2 YEAR VISIT

PATIENT STUDY ID: | TRIAL NO. 10-009 | COUNTRY NO. 0 0 1 | SITE NO | PATIENT NO. | PATIENT INITIALS [redacted] | ☐ No Adverse Events

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = **Secondary Procedure** ***(enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)**** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
18	☐1 ☒3 ☐2 ☐4	☒0 ☐1 ☐2	☒0 ☐3 ☐1 ☐2	5 unk 2003	☐1 ☐2 ☒3	☐1 ☐2 ☐3 Procedure Type Code†:___ ☐4 ___ days, Date: __/__/__ ☒5 Rheumatoid Workup Procedure Date: __/__/__	☐1 ☐4 ☒2 ☐3	
	☐1 ☐3 ☐2 ☐4	☐0 ☐1 ☐2	☐0 ☐3 ☐1 ☐2		☐1 ☐2 ☐3	☐1 ☐2 ☐3 Procedure Type Code†:___ ☐4 ___ days, Date: __/__/__ ☐5 ___ Procedure Date: __/__/__	☐1 ☐4 ☐2 ☐3	

Investigator's Signature | month 7 | day 29 | year 03

***Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

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13 = Hypertrophic Scarring
14 = Infection
15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify: Seronegative Rheumatoid Arthritis
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling
28 = Lactation Difficulties, specify:
29 = Other, specify:
30 = Other, specify:

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85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify:
92 = Other, specify.

WHITE ORIGINAL: MENTOR AFFILIATE YELLOW: MENTOR PINK: INVESTIGATOR SITE
6/15/00

5013

New Diagnosis of Connective Tissue Disease Patient Summaries

Study ID:
Cohort: Augmentation
DOS: 10/23/00
Implant Type: smooth round gel
Placement: subpectoral
MRI Substudy: NO
MRI Scan Dates: n/a
Investigator:

This patient was enrolled in the Core Gel Study on 10/23/00 in the Augmentation cohort. No rheumatology symptoms were documented at the baseline and 1 Year visits. At the 2 Year visit, the patient reported eh following symptoms: fatigue, insomnia, weakness, exhaustion, joint swelling, heel pain, frequent cramps, numbness of feet, night sweats, generalized aching joint pain, frequent muscle pain, numbness of hands, chronic cough, joint swelling, joint tenderness and swollen digits. She was referred to a rheumatologist,

ordered the following tests:

TSH	<0.004
T3 uptake	37
Free thyroxine	3.6

He reports these values are in the low-normal level. Her thyroid is in the upper limits of normal. She began taking bid 0.025 mg. He notes she has fibromyalgia syndrome and myofascial pain syndrome as a result of her thyroid deficiency. This consult was reviewed by a rheumatology expert who said she has hypothyroidism and as a result has thyroiditis, which is autoimmune in origin. The diagnosis should be reported as "Other:thyroiditis". This diagnosis was made 32 months from time of surgery.

At the 3 Year visit, all her symptoms had resolved with the exception of the following: loss of weight without dieting, joint swelling and tenderness.

This patient did not undergo an MRI scan. No rupture was suspected. She continues in the Core Gel Study under the care o . will return for her 4 Year follow-up visit in 2004

3/12
copy to Corzo/Notebook

Board Certified - Rheumatic Diseases

Washington, D. C. 20037

enrolled in CORE 10/23/00

RHEUMATOLOGY VISIT

October 21, 2002

Re: [redacted]

[redacted] continues to have arthralgias and myalgias but she is no longer getting arthritic inflammatory swelling. Her lab tests are completely negative for autoimmune arthritis and a bone scan done on October 4, 2002 was completely normal. The patient continues to have fatigue, myalgias, hair loss, a feeling of generalized coldness, and an inability to recover from her relatively aggressive exercise program which she has slowed down on. The patient does have a family history of thyroid disease in at least two relatives.

PHYSICAL EXAMINATION: Pulse 75, B/P 100/70, Weight 190-1/2 pounds. The patient has nonspecific soft tissue pain in the mid-thoracic and lower lumbar region without evidence of radicular pain and negative straight leg raising. What is interesting on her examination is that all her deep tendon reflexes are slowed, being only 1+ to trace positive with slow recovery time. Plantar reflex is negative. No sensory or motor deficit. No peripheral joint arthritis.

IMPRESSION:
1. Arthralgias.
2. Myalgias.
3. Fatigue.

The patient has had two thyroid tests in the low-normal level. She could certainly have an autoimmune thyroid problem. Thyroid antibody tests were ordered. Her thyroid is upper limits of normal and mildly normal. The patient was also empirically started on Synthroid 0.025 mg to be gradually increased over a month and we will reevaluate at that time.

RRR:
cc:

Thyroid antibodies negative

Rheumatic Diseases

January 28, 2003

Re: [redacted]

Dear Roger

I am pleased to report that [redacted] has apparently had a complete resolution of her musculoskeletal pain syndrome on Synthroid 0.15 mg daily.* While her thyroid deficiency did not appear to be severe and currently is being evaluated by her endocrinologist the patient also has fibromyalgia syndrome and myofascial pain syndrome, as a consequence of the apparent thyroid deficiency and I have seen other patients who get exaggerated responses in their fibromyalgia when they have a relatively minor thyroid deficiency. The patient is seeing ter this week to further assess her endocrine status but the patient tells me s else has come up medically. The patient is still challenged with her weight gain and currently, she is at 190 pounds but she has essentially a normal medical examination today and she is encouraged that she begin an exercise program and a weight reduction program. I have advised her not to consider any plastic surgery until she has lost some of the weight that she has gained. We will check her thyroid levels on her current dose of medication.

Sincerely,

RRR:mdj:mpg
cc:

* TSH is low - patient had raised her synthroid from 0.075 → 0.15 - will reduce synthroid to 0.125 & recheck thyroid level

ERROR: limitcheck
OFFENDING COMMAND:] ((j œ n $. G ł G>{ ,°b ª | 15 ‰.Æ z ~

STACK:

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